Standard No.CEA/MIS- 028

Clinical Establishment Act Standard for Diagnostic Centre

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Introduction

In 2010 Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them.

The Ministry has notified the "National Council for Clinical Establishments" and 'The Clinical Establishments (Central Government) Rules, 2012" under this Act vide Gazette. *This Act is applicable to all kinds of clinical establishments from the public and private sectors, of all recognized systems of medicine including single doctor clinics. The only exception will be establishments run by the Armed forces.*

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Medical Imaging Services (Diagnostic Centre)

1. Definition

1.1 Medical Imaging Services (Diagnostic centre) are the clinical establishment that conduct investigation/ therapy /procedures (which does not require overnight admission) of patients that provide information for diagnosis, prevention and treatment of disease or assessment of health.

1.2 The centre may exist as stand-alone centre or can be attached to a Hospital/Day Care Centre providing patient care. They include but are not limited to lab, imaging and non-imaging diagnostic services.

1.3 Imaging based therapy as well as radiation therapy is also included in broader definition due to their common requirements.

1.4 The centre are the establishments where various types of radiologic ultrasonic and electromagnetic imaging based investigation/ therapy with no overnight admission are conducted by a professional staff. Interpretation of the image is also provided.

2. Scope

S. No	Scope of service	Inclusive of
1	**Laboratory**	Refer to Laboratory Standards
2	**Medical Imaging Services including Nuclear Imaging - Conventional Radiology**	1) Portable/Mobile X-ray. 2) Installed X – ray 3) Fluoroscopy including Cath Lab* 4) Others
3	**Dental Radiology**	1) IOPA 2) OPG 3) CBCT 4) Others
4	**Mammography**	1) Mammography 2) Others
5	**Bone densitometry**	1) Dual Energy X ray Absorptiometry (DEXA)

		2) Quantitative Ultrasound(QUS) 3) Others
6	**Ultrasound**	1) General Ultrasound 2) Colour Doppler flow imaging 3) ECHO** 4) Others
7	**Computed Tomography (CT) Scan**	1) CT Imaging 2) Others
8	**Magnetic resonance imaging**	1) MRI imaging 2) Others
9	**Nuclear Medicine**	1) Gamma Camera/SPECT 2) Positron Emission Tomography (PET) 3) Thyroid probe 4) RIA (Radio Immuno Assay) 5) Fusion Imaging- PET CT, SPECT CT, PET MRI etc. 6) Others
10	**Medical Imaging based interventional procedures. Diagnostic and therapeutic vascular and non-vascular interventional procedures**	1) Vascular Procedures- Cath Lab, DSA Lab 2) Non Vascular Procedures- Non vascular interventional lab. 3) Others like RF, HFU, Laser, Cryo, breast intervention lab etc
11	***Nuclear Medicine Therapy**	1) Thyroid 2) Bone 3) Others like joints
12	**Radiation Oncology**	1) Simulator 2) CT Simulator 3) Linear Accelerator 4) Cyber Knife 5) Cobalt 60 unit/Gamma Knife 6) Brachytherapy 7) Others
13	**Non Imaging Diagnostics**	1) Electrocardiogram. (ECG). 2) Holter Monitoring (ECG & ABPM) 3) Echocardiogram (ECHO) 4) Tread Mill Testing (TMT) 5) Electroencephalography (EEG)

		6) Electromyography(EMG)/Evoke Potential (EP). 7) Somato-sensory Evoked Potential (SSEP) 8) Sleep Studies 9) Nerve Conduction Velocity (NCV) 10) Spirometry 11) Audiometry 12) Uroflowmetry (UF) 13) Others

* Also refer to Imaging based Vascular Interventional Procedures

** Also refer to non imaging diagnostic services

3. Infrastructure

3.1 Signage

3.1.1 **There shall be appropriate signage to facilitate the patient access:**

a) Prominent board/signage displaying the name of the establishment in local language at the gate or on/outside the building of the establishment.

3.1.2 **There shall be appropriate signage to provide the information regarding the services:**

a) Display of scope of services.

b) Name of the doctors with registration number.

c) Fee structure of the various services provided (refer to CEA 2010 rules & regulation).

d) Timings of the establishment (For e.g – from 8am -2pm).

e) Directional signage within the facility.

f) Mandatory informational signage as per applicable law e.g. PNDT Act.

3.1.3 **There shall be appropriate safety related signage**

a) Warning signage (as per AERB directive).

b) Restriction of access signage especially to radiation/magnetic zone.

c) Fire Exit signage.

d) Other safety hazards and caution signs e.g. hazards from electrical shock, inflammable articles, hazardous materials etc.

3.2 Other facility premises requirement

3.2.1 The centre shall be developed and maintained to provide safe, clean and hygienic environment for patients, their families, staff and visitors.

3.2.2 The centre shall be well illuminated and ventilated. There shall be provision of adequate water and electricity supply as per establishment's requirement, through direct or alternate sources.

3.2.3 The total area requirement can be broadly classified into two categories viz. Common Area and Imaging area. The former includes facilities such as reception, waiting, toilet, reporting, dispatch of reports, etc. The Imaging area includes space requirements for main equipment and for ancillary services. The facility shall be adequately provided with working space to allow orderly and logical placement of equipment and material so as to maintain safe operationsAnnexure 1.

3.2.4 The room housing all imaging and non-imaging diagnostic equipment shall have appropriate area to facilitate desired operations, easy movement of staff and patient positioning.It shall have adequate space for accommodating one patient couch, imaging and non-imaging equipment and examiner's chair; at the minimum.

3.2.5 The space requirement for main equipment in Imaging area shall be as per AERB requirement / applicable regulatory requirements (if any) and also as per the scope of service. The imaging area shall also include space for ancillary services like film processing unit/Dark room, patient preparation, patient monitoring, facility for storage (cabinet etc), facility for backup equipment like UPS/generator etc.

3.2.6 Appropriate structural shielding shall be provided for walls, doors, ceiling and floor of the room housing the radiation unit so that doses received by workers and the members of public are kept to the minimum and shall not exceed the respective annual effective doses as prescribed by the competent authority (AERB).

3.2.7 No two radiation based equipment shall be installed in the same room.

3.2.8 Common area can be shared between the different divisions/sections of the Diagnostic centre/HCO. Within the Diagnostic centre various work sections can also share the resources and space however not compromising the quality of work.

3.3 Furniture and Fixtures

3.3.1 The Furniture and Fixtures in the establishment shall be available in accordance with the activities and workload of the establishment. e.g. table, chair, couch, wheelchair/trolley, Medicine tray/trolley, storage cabinets etc.

3.3.2 The establishments providing indoor services e.g. interventional radiology, radiation oncology, nuclear medicine therapy shall have furniture and fixtures appropriate for the number of patients as per their scope. Please refer to hospital standards for details.

3.3.3 All furniture & fixtures shall be appropriately maintained to keep them functional.

4. Human Resource

4.1 The establishment shall have qualified staff as per the scope of service provided. Please refer to Annexure 2.

4.2 All establishments shall have the services of radiologist /related medical practitioner or a qualified technologist to operate the equipment.

4.3 The establishment shall have services of a qualified radiologist or related medical practitioner, registered with State/Central Medical Council of India, competent for interpretation and reporting.

4.4 Every department with radiation based services shall have a Radiological Safety Officer (RSO) of appropriate level having qualifications as prescribed and approved by the competent authority.

4.5 For every staff (including contractual staff), there shall be personal record containing the appointment order, documentary evidence of qualification and/or training (and professional registration where applicable).

5. Equipment/instruments/drugs

5.1 Appropriate equipment(s) shall be available to provide comprehensive service as per the scope within the facility. They include the following:

a) **Main equipment:** It shall be as per scope of service

b) **Support equipment:** It shall be as per therequirement of main equipment. e.g.—printer/ dry view/ dark room equipment/ computer based storage (PACS)/ injector

c) **Backup equipment:**UPS/ Server/ Inverter—mandatory for radiation based investigations and where contrasts injection/ interventional procedure are done.

d) **Resuscitation equipment**: Crash cart/ medicine tray, Defibrillator / Ambu's bag/ face mask, provision for oxygen (Cylinder/ piped gas source), suction apparatus,-- mandatory for emergency services and where contrast injection/ interventional procedure are done.

5.2 The centre shall prepare an exhaustive list of equipment required and available for general functioning of the centre as per the scope.

5.3 All equipment shall be maintained in good working condition. Periodic inspection, cleaning, maintenance of equipment should be done. An equipment log book should be maintained for all major equipment.

5.4 Maintenance contracts including warranty cards, telephone numbers of staff to be contacted in case of equipment malfunction shall be available on site. User manual shall be available readily for reference.

5.5 Periodic performance check/calibration check for all equipment should be done using reference standard/reference material.

5.6 Relevant QA/safety checks for radiation based services shall be carried out and reported by the RSO as per AERB guidelines

6. Drugs, Medical devices and Consumables

6.1 The centre shall have adequate drugs, medical devices and consumables commensurate to the scope of services.

6.2 Whether generic/branded drugs are used, they shall be of good quality and shall have appropriate label depicting their composition, strength, dosage, date of manufacture & expiry, warning & cautions for use, storage instruction etc as relevant. No vial or cut strips shall be kept without label.

6.3 The emergency drugs and consumables shall be available at all times (please refer to Annexure 3).

6.4 Drug storage shall be in a clean and safe environment and shall be in consonance with requirements of manufacturer.

6.5 Administration of drugs especially injections shall be done by qualified/trained medical personnel, authorized by law.

6.6 The radiation devices/implants and radiopharmaceuticals shall be handled at all stages as per AERB requirement/applicable laws and regulations.

7. Legal/Statutory Requirements

7.1 Every application shall be accompanied with the documents confirming compliance with local applicable regulations and law. For indicative list refer to Annexure 4. They shall be kept updated by timely renewal.

7.2 All statutes and regulatory requirements mandated through prevalent Acts like AERB & PC PNDT shall be complied with as per the scope of service. Refer to current AERB safety code and PC PNDT Act.

8. Record Maintenance and Reporting

8.1 The minimum medical records to be maintained and nature of information to be provided by the Clinical Establishment shall be as prescribed in rules of CEA Act.

8.2 Medical Records shall be maintained in physical or digital format.

8.3 Confidentiality, security and integrity of records shall be ensured at all times.

9. Basic Process

9.1 Patient Registration and billing

9.1.1 Unique identification number shall be generated for each patient registered along with the details regarding the test/imaging/procedure to be conducted and name and address of referring doctor.

9.1.2 The establishment shall inform the patient/relative/attendant about specific procedure and expectedcostinrelevantformatand language.

9.2 **Informed Consent**

9.2.1 Appropriate risk screening shall be done for all patients undergoing invasive procedures/examinations like MRI, I/V Contrast injections, Anaesthesia/Deep sedation.

9.2.2 Informed consent shall be obtained from the patient/ next of kin/ legal guardian as and when required as per the prevailing Guidelines / Rules and regulations in the language patient can understand (e.g. Before Invasive procedures, contrast injections, sedation etc).

9.3 **Imaging Process**

9.3.1 All imaging done shall be appropriate/relevant to the clinical requirement.

9.3.2 All images shall be labelled with the following minimum information:

a) patient identification,
b) examination date and
c) the side (right or left) of the anatomic site imaged.

9.3.3 Structure and format of report for communication to patient and/orreferrer shall be standardized.

9.3.4 Quality of images and report shall be checked through internal verification process.

9.3.5 Correct patient ID shall be confirmed on requisition slip, images, report and cover envelop at the time of dispatch of report.

9.3.6 All facilities providing radiation based services shall have procedures and equipment for appropriate shielding of patients/attendants/occupational radiation workers/environment.

9.3.7 ALARA (As Low As Reasonably Achievable) principle shall be used for all radiation based services.

9.3.8 In case of emergency there shall be provision for providing appropriate first aid and arrangement for safe transport of patient to another facility along with the required clinical/imaging information or notes.

9.3.9 Emergency regarding accidental radiation exposure/spillage shall be handled by qualified personnel as per AERB guidelines.

9.3.10 The establishment shall have appropriate sedation/anesthesia, clinical and emergency support before,duringandafterthe procedure (if applicable).

9.3.11 The establishment providing Diagnostic Radiology services shall have all

processes as per AERB guidelines under the supervision of RSO level I.

9.3.12 The establishment providing Nuclear Medicine services shall have all processes (including handling of radioactive material) as per AERB guidelines under the supervision of RSO level II.

9.3.13 The establishment providing Radiation Oncology services shall have all processes (including handling of radioactive source/material) as per AERB guidelines under the supervision of RSO level III.

9.3.14 The establishment carrying out Interventional Procedures shall have pre-defined policies and protocols for all critical activities (including monitoring of the patient before, during and after the procedure).

9.3.15 Handling of mobile/potable radiation units shall be as per AERB guidelines for maximum radiation safety.

9.3.16 The establishment providing Non Imaging diagnostic services shall have all processes as per good practice guidelines.

9.3.17 If the establishment has teleradiology facility, it shall comply with the existing laws (if any) and appropriate quality parameters.

9.2 Infection Control

9.2.1 The centre shall take all precautions to control infections like practicing hand hygiene, equipment cleaning protocols, sterilization of reusable instruments/ use of sterile disposable instruments etc.

9.2.2 Availability of clean water for hand washing /liberal use of sanitizer shall be maintained throughout the working hours of the Diagnostic Centre.

9.2.3 The environment of the centreshall be kept clean.Sanitation and hygiene of the toilets shall be maintained.

9.2.4 Mopping of all areas with disinfectant shall be done at least once a day.

9.2.5 Biomedical waste Management: Biomedical waste shall be managed in accordance with the current BMW management and handling Rules.

9.3 Safety considerations

9.3.1 Radiation safety of the patients/attendants/occupational radiation workers/environment shall be appropriate for the level of services provided as per AERB guidelines/safety codes.

9.3.2 Radiation safety officer shall be available as per the level of services provided.

9.3.3 The X-Radiation Warning Sign shall be displayed as AERB directives from time to time.

9.3.4 Radiation risk monitoring of personnel and the facility shall be done as per AERB guidelines e.g. maintenance and integrity check of PPE like lead aprons, gonadal shields etc; records of personnel radiation monitoring badges (TLD/film badge); transport & handling of RA material/source.

9.3.5 Security and safety of patients, staff, visitors and relatives shall be ensured by provision of appropriate safety installations and adoption of appropriate safety measures.

9.3.6 Electrical lines to the X-ray unit shall be separated from lines to other utilities. They shall be appropriately insulated for safety.

9.3.7 Fire alarms and all electrical installation shall comply with the safety regulations as per current outlined in IS regulations

Annexure 1
Infrastructure Requirement

Minimum space requirement shall be as follows:

Sl.No	Area	Sub area	Specification
1.	Common Area		The centre may have a common area for reception, waiting, reporting, dispatch of report, toilet(s) etc depending on the workload and scope of service. If the Imaging department is part of a hospital or nursing home; common area may be shared with the hospital, however in case of specific toilet or waiting area requirement as per guideline of regulatory body same must be available.
2.	Imaging area	Main Equipment	The equipment shall be placed as per specification laid down by manufacturer or AERB or any other legal/ regulatory body. For non-imaging diagnostic equipment appropriate area for accommodating one patient couch, equipment and examiner's chair shall be available.
3.		Ancillary Services	Depending on the scope of service of the imaging/ diagnostic centre allocated space for film processing unit/Dark room, patient preparation, patient monitoring, facility for storage (cabinet etc), facility for backup equipment like UPS/generator etc. shall be available in the imaging area.

Annexure 2

Human Resource Requirement

Minimum human resource requirement shall be as follows:

Sl. No.	Type& Modality	Minimum Requirement		Remarks if any
		For Operation of Equipment	For interpretation and Reporting	Additional manpower
1.	Imaging:Conventional Radiology Mammography Bone densitometry Computed Tomography (CT) Scan Magnetic resonance imaging	Radiologist /related medical practitioner/ Radiographer's/ X ray technologist	Radiologist /Related medical practitioner	As per AERB guidelines Radiological Safety Officer (RSO) level I
2.	Dental Radiology	Radiologist /Dentist/ Radiographer's/ X ray technologist	Raidiologist/ Dentist	As per AERB guidelines
3.	Ultrasound	Radiologist /related medical practitioner	Radiologist /Related medical practitioner	As per PNDT Guideline Nodal officer for ensuring compliance to PNDT Act
4.	Nuclear Medicine	Nuclear Medicine Specialist/Radiologist / related medical practitioner/ Nuclear Medicine technologist	Nuclear Medicine Specialist/ related medical Practitioner	As per AERB guidelines Radiological Safety Officer (RSO) level II for Nuclear medicine
5.	Imaging based therapy:	Radiologist /related medical practitioner	Radiologist /related medical practitioner	Radiological Safety Officer

	Intervention based therapeutic Procedures			(RSO) level I for radiation based imaging services Nurses, anaesthetist and other technicians as per scope
6.	Nuclear Medicine Therapy:	Nuclear Medicine Specialist/Radiologist / related medical practitioner/ Nuclear Medicine technician/technologist	Nuclear Medicine Specialist/ related medical Practitioner	As per AERB guidelines Radiological Safety Officer (RSO) level III for Nuclear medicine therapy services Nurses, anaesthetist and other technicians like Medical Physicist as per scope
7.	Radiation Oncology:	Radiation Oncologist/ Radiotherapist/ related medical practitioner/ Radiotherapy technician/technologist/ Medical Physicist/ Radiation Physicist/ Radiological Physicist	Radiation Oncologist/ Radiotherapist/ related medical practitioner	As per AERB guidelines Radiological Safety Officer (RSO) level III for Radiation therapy services Nurses,

				anaesthetist and other technicians like Dosimetrist, Physicist as per scope
8.	Non Imaging Diagnostics: Electrocardiogram. (ECG). Holter Monitoring (ECG & ABPM) * Echocardiogram (ECHO) Tread Mill Testing (TMT) Electroencephalography (EEG) Electroencephalography (EEG) Electromyography (EMG)/Evoke Potential (EP). Somato-sensory Evoked Potential (SSEP) Sleep Studies Nerve Conduction Velocity (NCV) Spirometry Audiometry Uroflowmetry (UF) Others	Related Medical Practitioners /Technicians of related field	Related Medical Practitioners /Technicians of related field	

Qualification/training/registration requirements:

Radiologist: M.B.B.S with post graduate Degree in Radiology/Radiodiagnosis (M.D.R.D) or Diploma in Radiology /Radiodiagnosis (D.M.R.D) or DNB in Radiology/Radiodiagnosis (The Degree/Diploma being recognised by and registered with Medical Council of India /State Medical Council)

Related Medical Practitioner: M.B.B.S with or without post graduate qualification, having minimum of six months training in the related field of work (The

Degree/Diploma being recognised by and registered with Medical Council of India /State Medical Council)

Radiation Safety Officer (RSO): Radiation Safety Officer level I/II/III registered with AERB

Level – IQualifications for RSO for Diagnostic Radiology:A post-graduate degree/diploma in Radiology/Radiodiagnosisrecognised by Medical Council of India or National Board of Examination, Ministry of Health and Family Welfare;

Or
A degree/post-graduate diploma/post graduate degree in Radiology/Radiodiagnosis Technology from an institution/university.

Level - IIQualifications for RSO for nuclear medicine (diagnostic) practice:A post-graduate degree/diploma in nuclear medicine recognised by Medical Council of India or National Board of Examination, Ministry of Health and Family Welfare;

Or
A degree/post-graduate diploma/post graduate degree in Nuclear Medicine Technology from an institution/university.

Level–IIIQualifications for RSO for nuclear medicine (therapeutic) practice: Post M.Sc. diploma/post graduate degree in radiological physics/medical physics or equivalent from a university.

Dentist: B.D.S with or without post graduate qualification, (The Degree/Diploma being recognised by and registered with DentalCouncil of India /State Dental Council)

Radiographer's/ X ray technologist: Radiographer's/ X ray technologist course (including in-field training in diagnostic radiology) passed from recognised institution/ board/ university.

Nuclear Medicine Specialist: M.B.B.S with post graduate Degree in Nuclear Medicine or Diploma in Nuclear Medicine or DNB in Nuclear Medicine. (The Degree/Diploma being recognised by and registered with Medical Council of India /State Medical Council)

Nuclear Medicine Technologist: A degree in nuclear medicine technology from recognised institution/ board/ university;

Or

A degree in science from an university; and post-graduate degree/diploma in nuclear medicine technology from recognised institution/ board/ university

NurseGNM registered with Nursing Council of India or state nursing council with minimum 6 months experience in imaging services

Anaesthetist: M.B.B.S with post graduate qualification in Anaesthesia or having minimum six months training in the anaesthesia and related field. (The Degree/Diploma being recognised by and registered with Medical Council of India /State Medical Council)

Radiation Oncology/Radiotherapy: Qualification and Experience of Personnel in Radiation Oncology Facility:

Radiation Oncologist:

a) A basic degree in medicine from a recognized university; and

b) A post-graduate degree in radiation therapy/radiation oncology or an equivalent qualification.

Medical Physicist/Radiation Physicist/Radiological Physicist:

a) A post graduate degree in physics from a recognized university, and

b) A post M.Sc. diploma in radiological/medical physics from a recognized university; and

c) An internship of minimum 12 months in a recognised well-equipped radiation therapy department.

OR

a) A basic degree in science from a recognized university, with physics as one of the main subjects; and

b) A post graduate degree in radiological/medical physics from a recognized university; and.

c) An internship of minimum 12 months in a recognised well-equipped radiation therapy department.

Radiological Safety Officer:A radiological safety officer shall have

a) Minimum qualifications required for a medical physicist/radiation physicist/radiological physicist as mentioned above; and

b) An approval from the competent authority to function as radiological safety officer.

Dosimetrist: A dosimetrist shall have:

a) A basic degree in science from a recognized university, with physics as one of the subjects;

b) A minimum of 2 year experience in dosimetry in a recognised well-equipped radiation therapy department.

Radiation Therapy Technologist: A radiation therapy technologist shall have

a) 10+2 or equivalent with science subjects from a recognized board; and

b) Two years' radiation therapy technologists' course, or equivalent, based on the minimum course content prescribed by the competent authority, from a recognized institution with in-field training in radiotherapy.

c) Minimum Personnel Requirements For Radiation Oncology Facility

Category	Staffing
1. Radiation Oncology	
(i) Chief Radiation Oncologist	One per centre
(ii) Radiation Oncologist	one additional, for each 400 patients treated annually. No more than 40 patients under treatment by a single physician, per day
2. Medical Physics	
(ii) Medical Physicist/Radiation Physicist	One per Centre, for up to 500
(iii) Radiological Physicist	Patients treated annually, additional in ratio of 1 per 500 patients treated annually.
3. Radiological Safety	

i)Radiological Safety Officer	One per centre
4. Radiation Therapy Technology	
(i) Chief Radiation Therapy Technologist	One per centre
(ii) Radiation Therapy Technologist	2 per teletherapy unit up to 40 patients treated daily per unit,4 per teletherapy unit up to 80 patients treated daily per unit.
(iii) Technologist (Simulator)	2 for every 500 patients simulate annually
(iv) Technologist (Brachytherapy)	as needed
5. Treatment Planning and Execution	
(i) Dosimetrist/ Physics Assistant	One per 500 patients treated annually
(ii) Technologist (Mould Room)	one per 600 patients treated annually
6. Auxiliary	
(i) Nurse	may be employed as per requirements
(ii) Social Worker	may be employed as per requirements
(iii) Dietician	may be employed as per requirements
(iv) Physiotherapist	may be employed as per requirements
(v) Occupation Therapist	may be employed as per requirements
(vi) Psychologist	may be employed as per requirements
(vii) Maintenance Engineer	may be employed as per requirements

*Nurse and Maintenance Engineer as required

Annexure 3

Drugs, Medical devices and consumables

List of Emergency Drugs and consumables (Essential in all stand alonecentres)

S. No.	Name of the Drug	Minimum Quantity
1	Inj Adrenaline	2 A
2	Inj Hydrocortisone	1 vial
3	Inj Atropine	1 Ampoule
5	InjAvil	1 Ampoule
6	InjPhenargan	1 Ampoule
7	Inj. Deriphyline	1 Ampoule
8	Inj. Frusemide	1 Ampoule
9	Inj. Metoclopramide	1 Ampoule
10	Inj. Dexamethasone	1 Ampoule
11	Inj. Diazepam	1 Ampoule
12	Inj. Dicyclomine Hydrochloride	1 Ampoule
13	Inj. 5% dextrose infusion	1 Vac
14	Inj. Normalsline	1 Vac
15.	Syringes	-
16.	Needles	-
17.	IV cannula	-

a) For emergency drugs and consumables essential in the hospital based radiology department/ Nuclear Medicine/ Radiation Oncology services/ Interventional services please refer to hospital standards
b) Other drugs and consumables shall be available as per the scope of services and workload.

c) Medical devices shall be available as per the scope of servicesand workload.

d) Spill kit- for spill management of Radiopharmaceuticals/contaminated body fluids shall be available as per requirement specified by AERB.

Annexure 4

List of Licenses and Statutory Obligations

This is an indicative list and all of them might not be applicable to all the MIS:

1) AERB Act and Rules of Safety Code
2) Building Permit (From the Municipal Corporation or appropriate body).
3) No objection certificate from the Chief Fire officer.
4) License under Bio- medical Management and handling Rules, 1998.
5) No objection certificate under Pollution Control Act.
6) Radiation Protection Certificate in respect of all X-ray and CT Scanners from AERB.
7) Excise permit to store Spirit.
8) Income tax PAN.
9) Permit to operate lifts under the Lifts and escalators Act (If applicable).
10) Narcotics and Psychotropic substances Act and License.
11) Sales Tax Registration certificate.
12) Vehicle registration certificates for Ambulances (If applicable).
13) Consumer protection Act, 1986.
14) Contract Act, 1982.
15) Copyright Act, 1982.
16) Customs Act, 1962.
17) Drugs & cosmetics Act, 1940.
18) Electricity Act, 1998.
19) Employees provident fund Act.
20) ESI Act, 1948.
21) Equal remuneration Act, 1976.
22) Hire Purchase Act, 1972.
23) Indian medical council Act and code of medical ethics, 1956.
24) Maternity benefit Act, 1961.
25) MTP Act, 1971.
26) Minimum wages Act, 1948.
27) National building code.
28) Negotiable instruments Act, 1881.
29) Payment of bonus Act, 1965.
30) Payment of gratuity Act, 1972.
31) Payment of wages Act, 1936.
32) Persons with disability Act, 1995.
33) PNDT Act, 1996 and registration (If applicable).
34) Protection of human rights Act, 1993.
35) PPF Act, 1968.

GLOSSARY

Adult	An individual who has capacity and is at least 18 years of age
Adverse drug event	Adverse event: Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment. Adverse drug reaction: A response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function. Adverse drug event: The FDA recognizes the term adverse drug event to be a synonym for adverse event. In the patient safety literature, the terms adverse drug event and adverse event usually denote a causal association between the drug and the event, but there is a wide spectrum of definitions for these terms, including harm caused by a a) Drug b) Harm caused by drug use, and c) A medication error with or without harm Institute of Medicine: “an injury resulting from medical intervention related to a drug”, which has been simplified to “an injury resulting from the use of a drug” Adverse drug events extend beyond adverse drug reactions to include harm from overdoses and under-doses usually related to medication errors. A minority of adverse drug events are medication errors, and medication errors rarely result in adverse drug events.
Ambulance	A patient carrying vehicle having facilities to provide unless otherwise indicated at least basic life support during the process of transportation of patient. There are various types of ambulances that provide special services viz. coronary care ambulance, trauma ambulance, air ambulance, etc.
Basic life support (BLS)	Emergency procedures performed to sustain life that include cardiopulmonary resuscitation, control of bleeding, treatment of shock, stabilization of injuries and wounds and first, aid. Basic life support consists of a number of life-saving techniques which are focused on the "ABC"s of emergency

	care: **Airway:** the protection and maintenance of patient airway including the use of airway adjuncts such as an oral or nasal airway **Breathing:** the actual flow of air through respiration, natural or artificial respiration, often assisted by emergency oxygen **Circulation:** the movement of blood through the beating of the heart or the emergency measure of CPR BLS may also include considerations of patient transport such as the protection of the cervical spine and avoiding additional injuries through splinting and immobilization.
Calibration	Calibration is a set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measured.
Magnetic Resonance Imaging (MRI).	A non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves
Mammography	A non-invasive radiological procedure used to take pictures of the breasts in order to diagnose tumours or cysts.
Medical equipment	Any fixed or portable non drug item or apparatus used for diagnosis, treatment, monitoring and direct care of patient.
Medical Record	Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care
Computerized Tomography.	A non-invasive radiological diagnostic procedure that may or may not include nuclear medical dye.
Emergency	A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious

	dysfunction of any bodily organ or part
PCPNDT Act	Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996, 2003
Positron Emission Tomography (PET scan)	A non-invasive radiological procedure producing a sectional view of the body constructed by positron-emission tomography.
Protocol	A plan or a set of steps to be followed in a study, an investigation or an intervention.
Safety	The degree to which the risk of an intervention/procedure, in the care environment are reduced for a patient, visitors and health care providers.
Scope of services	Range of clinical and supportive activities that are provided by a health care organization.
Sterilization	It is the process of killing or removing microorganisms including their spores by thermal, chemical or irradiation means.

Licensee: The person or entity to whom the license is issued. The licensee is held responsible for compliance with all applicable rules**.**

Mobile Equipment or Portable Equipment: Equipment intended to be moved or carried from one location to another between periods of use.

Magnetic Resonance Imaging (MRI): A non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves

Mammography: A non-invasive radiological procedure used to take pictures of the breasts in order to diagnose tumors or cysts.

Medical Emergency: A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ

Medical equipment: Any fixed or portable non drug item or apparatus used for diagnosis, treatment, monitoring and direct care of patient.

Positron Emission Tomography (PET scan): A non-invasive radiological procedure producing a sectional view of the body constructed by positron-emission tomography.

Patient: Includes but is not limited to any person who is suffering from an acute or chronic illness or injury or who is crippled, convalescent or infirm, or who is in need of obstetrical, surgical, medical, nursing or supervisory care.

PCPNDT Act: Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996, 2003.

Radiation: Gamma rays, X-rays or rays consisting of alpha particles, beta particles, neutrons, protons and other nuclear subatomic particles, but not sound or radiowaves, or visible, infrared, ultraviolet light.

Radiological Safety Officer (RSO): Any person who is so designated by the employer and who, in the opinion ofthe competent authority, is qualified to discharge the functions outlined in the Radiation Protection Rules, 1971.

Safety: The degree to which the risk of an intervention/procedure, in the care environment are reduced for a patient, visitors and health care providers.

Shall or Must: Compliance is mandatory.

Sterilization: It is the process of killing or removing microorganisms including their spores by thermal, chemical or irradiation means.

Sonologist": Sonologist" means a person who possesses any one of the medical qualifications recognized under the Indian Medical Council Act, 1956 or who possesses a postgraduate qualification in ultrasonography or imaging techniques or radiology;